THE COALITION FOR ANIMAL HEALTH

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July 22, 1997

Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Services
Room 1-23
Park Building
12420 Parklawn Drive
Rockville, MD 20857

RE: Docket No. 97N-0217 (Request for Comments on Development of Options to Encourage Animal Drug Approvals for Minor Species and Minor Uses)

The Coalition For Animal Health is comprised of the major national trade associations representing the animal production, animal feed, and animal health products industries, as well as the veterinary profession. The Coalition was an active participant in negotiations leading to enactment of the Animal Drug Availability Act of 1996 (ADAA), and we are pleased to respond to the agency's request for comments on potential ways to encourage animal drug approvals for minor species and uses.

Background

The Coalition is strongly committed to improving the availability of minor-species and minor-use drugs. We believe the problems in the overall drug-approval process that led to enactment of the ADAA are equally pronounced with respect to minor-species and minor-use drugs. These drugs by their very nature have an extremely limited market and provide a small return on their manufacturers' investment. The animal drug approval process in the United States has become so costly and time consuming that it is becoming increasingly difficult for animal health companies to produce major-species/use drugs and financially impossible for them to produce minor-species and minor-use drugs.

When originally introduced, S. 773 and H.R. 2508 – the bills that eventually became the ADAA – included statutory changes to the federal Food, Drug and Cosmetic Act aimed at streamlining the process by which minor-species and minor-use drugs are approved. Negotiations in 1996 between the Coalition and FDA's Center for Veterinary Medicine resulted in an agreement by the Coalition to recommend to Congress that the minor species/uses provision be dropped from the ADAA. In return, CVM pledged to propose a significant new process by which minor-species and minor-use drugs are approved. The enacted version of the ADAA requires CVM to put forth such a proposal by April 1998.

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The Coalition commends CVM for its timely publication of the above-referenced docket and for its leadership and commitment to reinventing the process by which minor-species and minor-use drugs are approved. We look forward to publication of a formal proposal by April 1998 and to the timely implementation of a new minor-species/use drug approval process. The Coalition believes these following comments will help facilitate the development of such a process.

Creating Additional Statutory Authority

We believe there should be a different, though not a more lax, standard for target animal safety and effectiveness in drugs targeted for minor species and minor uses. The Coalition, however, reiterates the commitment it made at the beginning of the process that led to ADAA enactment to drug approval procedures that provide strong human safety protection.

The Coalition in the strongest possible terms opposes labeling a minor-species or minor-use drug to reflect different standards in the approval process. The Coalition presumes that whatever standard ultimately is set for such drugs still will provide the basic assurance that the drugs are safe and effective. Labeling the difference in standards is likely to create the false impression that a minor-species or minor-use drug is somehow less safe or effective. Such labeling could have a chilling effect on the development and marketing of minor-species and minor-use drugs and would undermine the intent of the ADAA and CVM's minor-species/use initiative.

As to the best way to establish a different standard, the Coalition recommends CVM pursue a process by which drugs are given a vastly streamlined approval, to be followed by post-market surveillance. The Coalition represents drug sponsors, producers who use minor-species and minor-use drugs and the feed mills and veterinarians which administer them. All of these groups would enthusiastically support such a process; in fact, it seems one of the best possible options for encouraging additional minor species/use submissions and approvals. The Coalition recommends the agency give serious consideration to the American Sheep Industry Association's (ASI's) comments in this area. The Coalition agrees with ASI that human food safety data would need to be collected first. Additionally, the Coalition agrees with ASI that much of the necessary human food safety data for minor-species drugs, including appropriate residue depletion and withdrawal time data, can be obtained in many instances by utilizing data from closely related species.

Finally, the Coalition supports both the use of foreign market reviews and approvals and the use of primary review process external to the agency. Expert panels and compendia also could be utilized.

The Coalition does not presume to offer a legal interpretation as to which of the above-mentioned recommendations requires new statutory authority and which could be implemented administratively. The Coalition urges CVM to utilize existing authority wherever possible to effect changes in the minor-species/use approval process. The Coalition, however, stands ready to work in partnership with CVM where absolutely necessary to seek appropriate, mutually agreeable changes in statutory authority.

Administrative/Regulatory Changes

The Coalition would be willing to explore with CVM possible different manufacturing standards for minor-species and minor-use drugs, though – again – the Coalition does not want "different" to be construed as meaning "more lax" manufacturing standards. The Coalition would note that virtually all minor-species/use drugs will be produced in plants that generally operate under major-species/use manufacturing standards, and we have some reservation about the practicality of creating two sets of manufacturing standards in the same facility.

Utilizing the CVM strategy for aquatic species could be beneficial. The Coalition would welcome educational programs aimed at both drug sponsors and end users, and the Coalition cannot immediately identify any species in which such a program would not work.

Incentives

The Coalition conceivably could support some type of tax incentive or grant program aimed at encouraging the development of minor species/use drugs. Provided funding is available to ensure the NRSP-7 program can fulfill adequately its existing mission, we would be supportive of expanding the program to include production uses of drugs for food/fiber species and all uses on non-food/fiber species. We also could support creation of a similar program at FDA. We would caution that all of the above-mentioned options would require congressional appropriations or changes to the tax code. In light of the recent budget agreement, the Coalition feels compelled to note that these proposals may not be realistic politically. Similarly, the Coalition has reservations about the likelihood of private, philanthropic organizations being able to provide sufficient funding to spur minor-species/use research in a meaningful fashion.

All of the above-mentioned proposals have merit and should be investigated, but both the agency and the Coalition are limited in their ability to implement these proposals. As such, they should not be the cornerstone of an effort to encourage additional minor-species/use approvals. Rather, they should supplement core changes to the statutes and regulations that govern the drug approval process.

The Coalition could support market or label exclusivity, provided such exclusivity were fashioned in a manner that does not unnecessarily stifle competition among drug sponsors.

Extending Existing Legal Authority

The Coalition is interested in exploring additional ways to distribute minor-species/use drugs through medicated feeds; however, the Coalition at this time cannot support any change to AMDUCA, the ADAA or other statutes that would permit the prescription or extra-label use of animal drugs in feed. The Coalition believes its time and the agency's would be better spent examining ways to use the Veterinary Feed Directive (VFD) process, or some similar process, to allow extra-label use of drugs in animal feed.

Again, the Coalition appreciates the opportunity to comment on this docket, and we again commend CVM for its leadership in the effort improve the process by which minor-species and minor-use drugs are approved. We look forward to working with the agency the coming months to create and implement this improved process.

Respectfully submitted,

American Farm Bureau Federation
American Feed Industry Association
American Sheep Industry Association
American Veterinary Medical Association
Animal Health Institute
National Broiler Council
National Cattlemen's Beef Association
National Pork Producers Council
National Turkey Federation